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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. 98E-0308]

Determination of Regulatory Review Period for Purposes of Patent Extension; **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle

AGENCY: Food and Drug Administration, HHS.

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ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For animal drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent

was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the animal drug product **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle (eprinomectin). **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle is indicated for treatment and control of gastrointestinal nematodes (adults and fourth stage larvae, L<INF>4</INF>), lungworms (adults and L<INF>4</INF>), cattle grubs (all parasitic stages), lice, mange mites, and flies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle (U.S. Patent No. 4,427,663) from Merck & Co., Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 7, 1997, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle is 2,492 days. Of this time, 2,475 days occurred during the testing phase of the regulatory review period, while 17 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective: June 22, 1990. FDA has verified the applicant's claim that the date the investigational new animal drug application became effective was on June 22, 1990.

2. The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act: March 31, 1997. The applicant claims March 27, 1997, as the date the new animal drug application (NADA) for **IVOMEC**<Register> **EPRINEX**^{TM} Pour-On for Beef and Dairy Cattle (NADA 141-079) was initially submitted. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to NADA 141-079 was March 31, 1997, which is considered to be the initially submitted date for NADA 141-079.

3. The date the application was approved: April 16, 1997. FDA has verified the applicant's claim that NADA 141-079 was approved on April 16, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,255 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 8, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 4, 1999 publication in the Federal Register), for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket

number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 1998.
Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.
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